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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,059	08/02/2004	Bernd Stahl	STAH3007/REF	4218

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,059	STAHL ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-75* is/are rejected.

7)☒ Claim(s) *56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 Sep 2009 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 11 Sep 2009, in which claims 36-55 are canceled and new claims 56-75 are added.

This application is the 371 national stage entry of PCT/EP03/00505, filed 20 January 2003, claiming benefit of foreign priority document Germany 102 03 999.2, filed 1 February 2002. An English language translation of this foreign priority document is not of record.

Claims 56-75 are pending in the instant application and examined on the merits herein.

Objections Withdrawn

Applicant's Amendment, filed 11 Sep 2009, with respect to objections to claims 43 and 45 has been fully considered and is persuasive, as claims 43 and 45 are canceled.

This objection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment and Remarks, filed 11 Sep 2009, with respect to claims 36-55 rejected under 35 U.S.C. 112, first paragraph, as not providing enablement for the full scope of the claim has been fully considered and is persuasive, as claims 36-55 are canceled and with regard to the amended claims, as Duncan et al. and Jutras et al. provide evidence supporting enablement for the species methyl β-cyclodextrin with regard to *E. coli* and Roth et al. is drawn to viral infection. Further, Bar et al. (Appl. Microbiol. Biotechnol., 1994, 41, p574-577, cited in PTO-892) provides evidence suggesting that all cyclodextrins interact directly with *E. coli* bacterial cells (page 574, left column, Abstract) by virtue of either complexing ability and/or surface activity of cyclic oligosaccharides (page 574, right column, paragraphs 1-2). Therefore the state of the art supports the enablement for the scope of the amended claims.

This rejection has been **withdrawn**.

Applicant's Amendment and Remarks, filed 11 Sep 2009, with respect to claims 45 and 46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as claims 45 and 46 are canceled, and with

regard to the term "a probe" Applicant's Remarks filed 11 Sep 2009 clarify that the term is broad, but not indefinite.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 11 Sep 2009, with respect to claims 36 and 38-55 rejected under 35 U.S.C. 102(b) as being anticipated by Yoshikumi et al. (US Patent 4,451,457, issued 29 May 1984, of record) has been fully considered and is persuasive, as claims 36 and 38-55 are canceled, and Yoshikumi et al. specifically does not disclose the method wherein the subject has a disease caused by said pathogenic intracellular bacteria as required by the claims as amended.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 11 Sep 2009, with respect to claims 36-51 and 53 rejected under 35 U.S.C. 102(b) as being anticipated by Anand et al. (US Patent 5,221,669, provided by Applicant on IDS filed 2 August 2004) has been fully considered and is persuasive, as claims 36-51 and 53 are canceled, and Anand et al., drawn to treating viral infections, does not disclose the method wherein subject has a disease caused by said pathogenic intracellular bacteria as required by the claims as amended.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 11 Sep 2009, with respect to claims 36-43, 46, 48-51 and 53 rejected under 35 U.S.C. 102(b) as being anticipated by Roth et al. (WIPO

publication WO/90/00596, provided by Applicant on IDS filed 2 August 2004) has been fully considered and is persuasive, as claims 36-43, 46, 48-51 and 53 are canceled, and Roth et al., drawn to treating viral infections, does not disclose the method wherein subject has a disease caused by said pathogenic intracellular bacteria as required by the claims as amended.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 11 Sep 2009, with respect to claims 36-44, 46 and 48-51 rejected under 35 U.S.C. 102(b) as being anticipated by Nelson (US Patent 6,261,540, of record) has been fully considered and is persuasive, as claims 36-44, 46 and 48-51 are canceled, and Nelson does not specifically disclose the method wherein the subject has a disease caused by said pathogenic intracellular bacteria as required by the claims as amended.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 11 Sep 2009, with respect to claims 36-51 and 53 rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (US Patent 4,020,160, of record) has been fully considered and is persuasive, as claims 36-51 and 53 are canceled, and Bernstein does not specifically disclose the method wherein the subject has a disease caused by said pathogenic intracellular bacteria as required by the claims as amended.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 11 Sep 2009, with respect to claims 36, 38-43, 46-51 and 53 rejected under 35 U.S.C. 102(b) as being anticipated by Castro Hermida et al. (Parasitol. Res., 2001, 87, p449-452, of record) has been fully considered and is persuasive, as claims 36, 38-43, 46-51 and 53 are canceled, and Castro Hermida et al., drawn to reducing infection by protozoa, does not specifically disclose the method wherein the subject has a disease caused by said pathogenic intracellular bacteria as required by the claims as amended.

This rejection has been **withdrawn**.

Claim Objections

Claim 56 is objected to because of the following informalities:

- Claim 56 does not end in a period, and

- Claim 56 at line 21 appears to recite the typographical error "phosphocholiny" instead of "phosphocholinyl-".

Appropriate correction is required.

The following are new grounds of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56-63, 65-68, 70-72 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirai et al. (US Patent 4,616,008, issued 7 Oct 1986, cited in PTO-892).

Hirai et al. discloses a method of treating a bacterial infection by oral administration of a composition comprising a cephalosporin antibiotic and a cyclodextrin (column 1, lines 5-10). Hirai et al. discloses the cyclodextrin includes alpha-, beta-, and gamma-cyclodextrin (column 17, lines 25-30) and derivatives tri-O-methylcyclodextrin, di-O-methylcyclodextrin, and triaminocyclodextrin (column 17, lines 30-40). Hirai et al. discloses the composition further contains a carrier such as the binders starch or cellulose (column 18, lines 5-10), which are biopolymers. Hirai et al. discloses the composition is useful in the treatment of infectious diseases in human and mammals caused by bacteria, for example respiratory tract infections and urinary tract infections caused by bacteria such as *E. coli* (column 19, lines 45-60). A human that has an infectious disease is necessarily a sick person. Therefore the invention of disclosed by Hirai et al. as a whole meets the limitations of instant claims 56-63, 65-68, 70-72 and 75.

The instant invention as excerpted from claim 56, "administering to a subject in need thereof an orally or per os a composition selected from the group consisting of a liquid food composition, a solid food composition, a dietetic composition, and a pharmaceutical composition, wherein the subject has a disease caused by said pathogenic intracellular bacteria, **and wherein the composition comprises one cycloglycan** selected from the group consisting of cycloglycans having a ring-shaped

base structure of 4 to 20 monosaccharides in the ring…" (emphasis added) is deemed to encompass the method of administering the composition of Hirai et al. comprising a cephalosporin antibiotic **and** a cyclodextrin because the transitional phrase "comprising" is inclusive or open-ended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56-72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (US Patent 4,616,008, issued 7 Oct 1986, cited in PTO-892).

Hirai et al. discloses as above.

Hirai et al. does not specifically disclose the method further comprising administering the composition with a probe to the stomach of a human subject (instant claims 62 and 67). Hirai et al. does not specifically disclose the method wherein the cycloglycan is administered once daily in an amount of at least 1 mg/kg of body weight to a human subject (instant claims 64 and 69).

Hirai et al. the dose varies depending on the subject to be treated, the symptom and other factors, but generally the dose in a human is 50 mg to 1 g of the cephalosporin compound per oral administration administered in such dose 2 to 4 times daily (column 19, lines 55-60). Hirai et al. teaches the cephalosporin compound in a composition that is preferably 15 to 50% by weight cyclodextrin relative to the cephalosporin compound (column 17, lines 45-50). Hirai et al. teaches an embodiment wherein two doses are administered at one time together with water to a beagle dog (column 25, Test Example 1 at lines 40-65 and column 26, Test Example 2 at lines 1-25).

It would have obvious to one of ordinary skill in the art at the time of the invention to optimize the dose of the composition taught by Hirai et al. comprising a cephalosporin compound and a cyclodextrin because Hirai et al. teaches the dose is varied depending on treatment factors. An adult man is approximately 60 kg, such that the upper limit of the dosage range, 1 g of the cephalosporin compound, gives 150 to 500 mg cyclodextrin relative to the cephalosporin compound, or at least 1 mg/kg of body weight to the human subject. It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the dosage once daily because the Hirai et al.

teaches the dose is varied depending on treatment factors and Hirai et al. teaches an embodiment wherein two doses are administered at one time. It would have been obvious to one of ordinary skill in the art to administer the composition with water to a human subject, such that the water would go to the stomach of a human subject. The term "probe" is interpreted to encompass any substance that is used to obtain specific information for diagnostic or experimental purposes, therefore the water is interpreted as a probe of the uptake of the composition taught by Hirai et al.

Claims 73 and 74 rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. (US Patent 4,616,008, issued 7 Oct 1986, cited in PTO-892) as applied to claims 56-72 and 75 above, in view of Thornsberry (Clinical Infectious Diseases, 1992, 14(2), pS189-S196, cited in PTO-892).

Hirai et al. teaches as above.

Hirai et al. does not specifically teach the method wherein the subject has a disease caused by *Listeria* (instant claim 73) or *Salmonella* (instant claim 74).

Thornsberry teaches that cephalosporin compounds are known to have antibiotic activity against *Listeria monocytogenes* (page S189, abstract) and *E. coli* and *Salmonella species* (page S191, left column, paragraph 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Hirai et al. in view of Thornsberry to treat a subject having a disease caused by *Listeria* or *Salmonella*. It is well-known in the antibiotic treatment arts to select antibiotics that are known to have activity against the bacterial infectious

agent. Thornsberry teaches cephalosporin compounds known at the time of the invention that have activity against *Listeria* or *Salmonella*. Therefore it would have been obvious to one of ordinary skill in the pertinent art to apply the treatment taught by Hirai et al. to bacterial infections that the cephalosporin antibiotic taught by Hirai et al. is known to have activity against with a reasonable expectation of success.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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